

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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POLICY

Voluntary Public

Date: 2/12/2016

GAIN Report Number: E16013

EU-28

Post: Brussels USEU

Legal Opinion on New Plant Breeding Techniques (NBTs) to be Published Soon

Report Categories:

Biotechnology and Other New Production
Technologies

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Report Highlights:

The legal analysis carried out by the European Commission (EC) on whether or not certain New Plant Breeding Techniques, known as NBTs, fall under the scope of the European GMO legislation is expected to be published during the first half of 2016. The Commission's legal interpretation will likely impact the use of these technologies in both private and public sectors' efforts to innovate plant breeding in the EU and globally.

General Information:

What Are NBTs?

Plant breeding has been practiced since the beginning of human civilization and makes use of variations in plant genomes to develop new crop varieties to meet the demand of farmers and consumers. Changes and variation in plant genomes are essential drivers for plants to adapt to their environment. Over the years, the development of breeding techniques has continued to progress rapidly resulting in more sophisticated methods to create plants with new traits. Plant breeders around the world are increasingly using what the EC termed New Plant Breeding Techniques (NBTs).

These so called NBTs refer to genome editing and modification techniques, which allow the introduction of sequence-specific changes in the plant genome. These precision-based mutation approaches can be used without creating side-effects, such as additional mutations throughout a genome, unlike chemical or radiation induced mutagenesis.

NBTs are used in plant breeding of major crops such as corn and soybean, vegetables, commodity and specialty crops by both the private and public sectors. The development of new technologies in the plant breeding sector over the last couple of years has made the breeding process faster and more targeted, lowering the production costs, and speeding up innovation around the world. NBTs are a promising new field for the agri-food sector, not only for plant breeders, but also to meet global challenges of population growth, climate change and food security.

According to [the NBT platform](#), the European plant breeding industry is a world leader in terms of innovation, representing a market value of more around \$ 9.7 billion (€ 8.6 billion). A significant share of the more than 7,000 companies in the EU seed sector are Small-to-Medium-Size Enterprises (SMEs) that depend on innovation and access to technology to remain competitive.

The Need for Legal Certainty

The current EU GMO-legislative framework, [EU Directive 2001/18/EC](#), does not reflect the progress made in the development of new techniques. It was first put in place to deal with the potential risks of transgenic techniques, referring to the introduction of foreign DNA into an organism, but there is no existing reference to NBTs in its GMO definition. It is also focused on the technique used to produce a new plant and not on the final product.

EU scientists, plant breeders, biotech industry and Member States (MS) urged the EC to clarify the legal status of the NBTs and their application. The overall concern is that an expensive and lengthy authorization procedure would be necessary for these techniques and its products, even in cases where no foreign DNA is contained in the resulting end product or where these products are completely indistinguishable from conventionally bred crops.

During the Agriculture and Fisheries Meeting of the European Council on October 22, 2015, several MS agreed that the legal framework for the use of NBTs should be clarified as there are a range of different opinions expressed by legal experts. Furthermore, in December last year, the European Parliament's (EP) Agriculture Committee organized a public hearing on NBTs to clarify the issue and stress the

importance of the legal interpretation to several stakeholders as some MS are proceeding with their own legal interpretation due to the EU-wide legal uncertainty. The MS first raised this issue with EC in 2007.

Status of the Legal Analysis

The EC is currently working on the legal analysis on whether or not certain NBTs should fall under the EU's GMO legislation. In October 2015, the EC asked the European Food Safety Authority (EFSA) for a scientific clarification with regard to the definitions in Directive 2001/18/EC and some specific techniques.

The EC set up a New Techniques working group back in 2007 to address the NBTs issue after a request from the national authorities.

The following NBTs have been considered by the Working Group:

- 1) Zinc Finger Nucleases (ZFN, representative of a growing group of related techniques more commonly referred to as Site-Directed Nucleases (SDN), including amongst others ZFN-1/2/3, TALENs, Meganucleases and CRISPR-Cas)
- 2) Oligonucleotide Directed Mutagenesis (ODM)
- 3) Cisgenesis
- 4) RNA-dependent DNA methylation (RdDM)
- 5) Grafting (non-GMO scion on GMO rootstock)
- 6) Reverse breeding
- 7) Agro-infiltration 'sensu stricto'

The publication of the EC's legal analysis had reportedly been delayed several times. The EC was expected to come out with their legal interpretation on NBTs in February 2016. The new timeline refers to the end of March 2016, but recently noted it will be published during the first half of 2016.

The EC's legal interpretation is expected to facilitate the harmonization of MS approaches to NBTs, but it is the sole prerogative of the European Court of Justice to provide a final and binding opinion on the interpretation of EU law. The EC's legal interpretation will be presented to MS and stakeholders, as well as representatives from the EP.